

### REMARKS

Claims 1, 3, 4, and 10-13 are pending in the present application. Claims 2, 5-9, and 14-44 were previously cancelled. In this response, the subject matter of claim 10 (instructions for use) has been added to claim 1. Thus, claim 10 has been cancelled. Dependent claims 3 and 4 have also been amended so that claim 1 provides appropriate antecedent basis. Accordingly, claims 1, 3, 4, and 11-13 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

#### *Claim Rejections – 35 USC § 103*

A. Claims 1, 3, 4, and 10-13 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. 5,962,532 to Campbell and Ann Jones et al. (Clinical toxicology, abstract only) (“Ann Jones”) in view of Wholehealthmd and U.S. 5,910,512 to Conant. Although Campbell does not teach the claimed kit and second component, the Office states that it would have been obvious to a skilled artisan to first apply capsaicin for its intended pharmacological effect (Campbell) and then apply a soapy solution (Wholehealthmd) or an oily solution (Ann Jones et al.) to remove the irritant effect. The Office further states that the solutions, specifically oily solutions, solubilize capsaicin to the claimed percent to successfully remove the irritant effect because Conant teaches that capsaicin is soluble in alcohol, grease, chloroform, etc.

Applicants strongly disagree with this rejection. Claim 1 has been amended to recite that the second composition includes about 60 to about 99 percent polyethylene glycol by weight and that the kit comprises instructions for use. Support for this amendment is found, among other places, at paragraphs 23, 47, and 51 of the specification as originally filed.

The instructions include the steps of applying the second composition to the bodily surface exposed to the capsaicin-containing first composition, and removing the second composition from the exposed bodily surface about one minute after the second composition has been applied. In view of this amendment, obviousness has not been established because the cited references, alone

or in combination, lack disclosure of the claimed amount of polyethylene glycol in the second composition and the claimed instructions for use that includes the step of removing the second composition after about one minute. The Office has admitted that Campbell fails to teach the kit and the second composition (see page 2 of the final Office Action dated June 16, 2009). Thus, there cannot be any disclosure in Campbell of instructions for using the second composition.

With respect to Ann Jones, the cited reference also fails to describe the amount of polyethylene glycol in the second composition and the steps for removing the second composition in the instructions for use, as claimed. Although various (second) compositions were experimentally used to determine their effect on “chile burn” (i.e., burning pain, irritation, and erythema) of the hands, there is no disclosure of whether these compositions contain about 60 percent to about 99 percent by weight polyethylene glycol. Additionally, Ann Jones fails to describe instructions for use of the composition where the second composition is removed about one minute after it has been applied. Instead, the experimental treatment described in the cited reference consists of five treatment cycles, where each treatment cycle includes immersion of the test subject’s hands in each test composition for 15 minutes, for a total application time of 75 minutes (see page 486, second full paragraph). This application time is significantly longer than the claimed about one minute. After each immersion the hands were removed, dried (but not rinsed) with a paper towel, and then air dried for five minutes. Based on this disclosure, Applicants submit that Ann Jones wholly fails to teach or suggest removal of the (second) composition. Even if the removal step was taught, the cited reference clearly fails to teach or suggest removal of the (second) composition about one minute after it has been applied.

Neither Wholehealthmd nor Conant cure the penetration enhancer and instructions for use defects in Campbell and Ann Jones. Wholehealthmd describes hand washing with warm soapy water. Conant completely lacks disclosure of a second composition. Applicants submit that because Wholehealthmd and Conant do not cure the deficiencies in Campbell and Ann Jones, it cannot be said that Campbell and Ann Jones in view of Wholehealthmd and Conant render the instant claims obvious. Moreover, one of skill would not have any reason to use Ann Jones as a primary reference in establishing a case of obviousness due to the significant difference in

application time of the (second) composition (75 minutes versus about one minute) and the requirement that the hand immersions be repeated five times. Applicants assert that one of skill would not look to a reference advocating repeated immersions as a remedy because of its inconvenience and time consuming nature.

At least in view of the above, withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

**B.** Claims 1, 3, 4, and 10-13 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. 2002/0002406 to Robbins et al. ("Robbins") and Ann Jones et al. in view of Wholehealthmd and U.S. 5,591,512 to Conant. Although Robbins fails to teach the claimed kit and a second composition to solubilize capsaicin and the instructions for use, the Office states that it would have been obvious to one of ordinary skill to include such components in view of the teachings of Ann Jones, Wholehealthmd, and Conant.

Applicants disagree with this rejection. The Office concedes that Robbins fails to teach a kit, a second composition, and instructions for use (see page 5 of the final Office Action dated June 16, 2009). As discussed above, Ann Jones, Wholehealthmd, and Conant also fail to disclose these claim elements. Given that Ann Jones, Wholehealthmd, and Conant do not cure the defect in Robbins, the combination of cited references to not render the instant claims obvious.

Accordingly, withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 524522000500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By: 

Lisa Amir

Registration No.: 48,199

MORRISON & FOERSTER LLP

755 Page Mill Road

Palo Alto, California 94304-1018

(650) 813-5674